UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

June 25, 2003

MEMORANDUM

EPA File Symbol: 66330-UI CAPTEVATE 68 WDG
DP Barcode: D289843
Decision Code:211712
Case No: 065274
Submission: S628312
PC Codes: 090209 Fenhexamid
081301 Captan

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
6/25/2003

To: Carl Grable/Mary Waller, PM 21
Fungicide Branch
Registration Division (7505C)

Registrant: ARVESTA CORPORATION

ACTION REQUESTED: "Please review the attached data and waiver request to support registration of this combination product. MRIDs 458297-02 and -03 and waiver request in volume 5..."

BACKGROUND: The proposed product EPA File Symbol 66330-UI CAPTEVATE™ 68WDG FUNGICIDE has the following label ingredient declaration:

Active Ingredients:

Fenhexamid	14.3%
Captan	53.6%
Captan-Related Derivatives	1.2%
Inert Ingredients:	30.9%

This package contains 3 acute toxicity studies conducted on material identified as CaptEvate 67.9 WDG, containing 13.62% Fenhexamid and 53.86% Captan: rat acute oral LD_{50} (MRID 45829702); rat acute dermal LD_{50} (also in MRID 45829702); and rabbit primary skin irritation (also in MRID 45829702). There is also a rat inhalation LC_{50} study conducted on material identified as Captan 80 WP (MRID 45829703). In addition, the registrant has submitted requests for waivers of inhalation LC_{50}, primary eye irritation and dermal sensitization studies on CaptEvate 68 WDG, citing existing inhalation studies on Fenhexamid and Captan (including the study in MRID 45829703), and stating acceptance of labeling which will identify the proposed product as a toxicity category I eye irritant and dermal sensitizer.

COMMENTS AND RECOMMENDATIONS:

1. The 3 submitted acute toxicity studies have been classified as acceptable. It is noted that the inhalation toxicity study (MRID 45829703), while acceptable, was conducted on Captan 80 WP. However, the results of this study can be used by the registrant to support a waiver request for an inhalation study on CaptEvate 68 WDG.

2. TRB recommends for a waiver of the inhalation study, as information provided by the registrant (including particle size data) indicates a low order of toxicity to the final product (toxicity category IV). The submitted inhalation LC_{50} study on Captan 80 WP provides additional support to the registrant's position.

3. As the registrant is accepting toxicity category I labeling (including the signal word DANGER) for eye irritation potential and labeling indicating this proposed product is a potential dermal sensitizer, TRB recommends for waiver of these studies. If the registrant wishes to subsequently revise their label, then the appropriate acute toxicity studies will be necessary.

4. The following is the acute toxicity profile for CaptEvate 68 WDG based on the results of the submitted acute toxicity studies, TRB's recommendation that the inhalation study requirement be waived, and acceptance of the registrant's labeling of the product as being in toxicity category I by the eye exposure route and as a dermal sensitizer:

Study Type	Tox. Cat.	Classification & MRID #
Oral LD_{50} (rat)	Tox. Cat. III	Acceptable (MRID 45829702)
Dermal LD_{50} (rat)	Tox. Cat. IV	Acceptable (MRID 45829702)
Inhalation LC_{50}(rat)	Tox. Cat. IV	Waived[a]
Eye Irritation (rabbit)	Tox. Cat. I	Waived[b]
Dermal Irritation (rabbit)	Tox. Cat. IV	Acceptable (MRID 45829702)
Dermal Sensitization (guinea pig)	Sensitizer	Waived[c]

[a]Registrant has submitted sufficient information, including an inhalation LC_{50} study on an 80% Captan formulation, to demonstrate that the proposed product has a low degree of toxicity by this exposure route.
[b]Registrant will accept toxicity category I labeling (including the signal word DANGER) for eye exposure hazard.
[c]Registrant will accept labeling identifying the proposed product as a dermal sensitizer.

5. Based on the acute toxicity profile above and the proposed uses, the following would be the precautionary labeling for this product, as obtained from the Label Review System:

PRODUCT ID #: **066330-00048**

PRODUCT NAME: CAPTEVATE 68 WDG

PRECAUTIONARY STATEMENTS

SIGNAL WORD: DANGER

SPANISH SIGNAL WORD: PELIGRO
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A).

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I Primary Eye Irritant toxicity. The following statements are suggested types of information that may be included, if applicable:
- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.
NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (870.1100, formerly §81-1)

Product Manager: 21 **Reviewer:** Byron T. Backus, Ph.D.
MRID No.: 45829702 (note: 2 other studies included in this MRID No.)

CITATION: Kuhn, J.O. CaptEvate 67.9 WDG: Final Report: Acute Oral Toxicity in Rats. Laboratory Study No. 7039-02; included under Arvesta TMN-0070. Unpublished study prepared by STILLMEADOW, Inc. Study Completion Date: September 5, 2002. MRID 45829702.

STUDY SPONSOR AND SUBMITTER: Arvesta Corporation, San Francisco, CA

TEST MATERIAL: CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot: 0279954, Prod #: 823, TCR: 2993. Described as fine rust brown granules containing 13.62% Fenhexamid and 53.86% Captan.

SPECIES: Rat; albino, Sprague-Dawley
AGE(at dosing): Young adult (approx. 8 weeks)
WEIGHT (fasted): Males: 243-277 g; Females: 162-196 g
SOURCE: Texas Animal Specialties, Humble, TX

EXECUTIVE SUMMARY: ***In an acute oral toxicity study (MRID 45829702), groups of 5 male & 5 female fasted (period of fasting not specified; fasted body wts: males: 243-277 g; females: 162-196 g) 8-week (approximately) old albino Sprague-Dawley rats (source: Texas Animal Specialties, Humble, TX) were orally gavaged with doses of 2000 or 5050 mg/kg of the granular solid CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot 0279954, Prod #: 823, TCR: 2993, containing 13.62% Fenhexamid and 53.86% Captan as active ingredients. For dosage, the test article was mixed with deionized water to produce a 40% w/v concentration and the resulting mixture was administered at volumes of 5.0 mL/kg (2000 mg/kg group) and 12.6 mL/kg (5050 mg/kg group).***

At 2000 mg/kg there was no mortality (0/5 males & 0/5 females died). At 5050 mg/kg all rats died (5/5 males & 5/5 females died). Symptoms at 2000 mg/kg included very slight to moderate diarrhea (present in most males and in all females) and, in females only, piloerection (present in all at 2 hrs after dosage) and sensitivity to the touch (present in all on days 1, 2 & 3). All males had recovered by day 1 and all females had recovered by day 4. At 5050 mg/kg symptoms included diarrhea, activity decrease, piloerection & salivation. All (5/5) females and most (4/5) males died by day 1; one male was dead on day 6.

All rats dosed at 2000 mg/kg gained weight in the period from day 0 (day of dosage) to 7 and again from day 7 to 14. At post-sacrifice necropsy, no abnormalities were found in any of the 2000 mg/kg rats.

Rats dosed at 5050 mg/kg which died by day 1 had necropsy findings which included muzzle fur matted & brown/yellow, mottled lungs, brown/white liquid in stomach and small intestine, large intestine empty. The animal which died by day 6 had pale lungs, brown liquid in stomach, brown gel in the small intestine and red/orange gel in the large intestine.

Oral LD50 (rat) M > 2000 mg/kg (0/5 died at this dose); < 5050 mg/kg (5/5 died at this dose).
Oral LD50 (rat) F > 2000 mg/kg (0/5 died at this dose); < 5050 mg/kg (5/5 died at this dose).
Oral LD50 (rat) combined > 2000 mg/kg (all survived); < 5050 mg/kg (all died)

The granular solid CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot 0279954, Prod #: 823, TCR: 2993, containing 13.62% Fenhexamid and 53.86% Captan as active ingredients is in toxicity category III for oral toxicity, as the rat oral LD50 > 2000 mg/kg but < 5050 mg/kg.

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 7), Quality Assurance (p. 9), and [No] Data Confidentiality (p. 6) statements are provided. There is no flagging statement.

Procedure (including deviations from 870.1100): "The test substance was mixed with deionized water to produce a 40% w/v concentration. An individual dose was calculated for each animal based on its fasted [note: period of fasting is not specified in this report] body weight and administered by gavage at a volume ranging from 5.00 mL/kg at the 2000 mg/kg level to 12.6 mL/kg at the 5050 mg/kg level. Each dose was administered using an appropriately sized syringe and stainless steel ball-tipped intubation needle..."

Results:

Dose (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Total
2000	0/5	0/5	0/10
5050	5/5	5/5	10/10

The test material was administered as a 40% w/v mixture in deionized water.

Observations: At 2000 mg/kg there was no mortality (0/5 males & 0/5 females died). At 5050 mg/kg all rats died (5/5 males & 5/5 females died). Symptoms at 2000 mg/kg included very slight to moderate diarrhea (present in most males and in all females) and, in females only, piloerection (present in all at 2 hrs after dosage) and sensitivity to the touch (present in all on days 1, 2 & 3). All males had recovered by day 1 and all females had recovered by day 4. At 5050 mg/kg symptoms included diarrhea, activity decrease, piloerection & salivation. All (5/5) females and most (4/5) males died by day 1; one male was dead on day 6.

All rats dosed at 2000 mg/kg gained weight in the period from day 0 (day of dosage) to 7 and again from day 7 to 14.

Gross Necropsy: At post-sacrifice necropsy, no abnormalities were found in any of the 2000 mg/kg rats.

Rats dosed at 5050 mg/kg which died by day 1 had necropsy findings which included muzzle fur matted & brown/yellow, mottled lungs, brown/white liquid in stomach and small intestine, large intestine empty. The animal which died by day 6 had pale lungs, brown liquid in stomach, brown gel in the small intestine and red/orange gel in the large intestine.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (870.1200, formerly §81-2)

Product Manager: 21 **Reviewer:** Byron T. Backus, Ph.D.
MRID No.: 45829702 (note: 2 other studies included in this MRID No.)

CITATION: Kuhn, J.O. CaptEvate 67.9 WDG: Final Report: Acute Dermal Toxicity in Rats. Laboratory Study No. 7040-02; included under Arvesta TMN-0070. Unpublished study prepared by STILLMEADOW, Inc. Study Completion Date: September 5, 2002. MRID 45829702.

STUDY SPONSOR AND SUBMITTER: Arvesta Corporation, San Francisco, CA

TEST MATERIAL: CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot: 0279954, Prod #: 823, TCR: 2993. Described as fine rust brown granules containing 13.62% Fenhexamid and 53.86% Captan.

SPECIES: Rat; albino, Sprague-Dawley
AGE(at dosing): Young adult (59 days)
WEIGHT: Males: 262-285 g; Females: 200-204 g
SOURCE: Texas Animal Specialties, Humble, TX

EXECUTIVE SUMMARY: ***In an acute dermal toxicity study (MRID 45829702), 5M & 5F young adult (59 days old) Sprague-Dawley albino rats (source: Texas Animal Specialties, Humble, TX) received a 24-hr semi-occluded dermal exposure to a dosage of 5050 mg/kg of the granular solid CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot 0279954, Prod #: 823, TCR: 2993, containing 13.62% Fenhexamid and 53.86% Captan as active ingredients, formulated with deionized water at 0.3 mL/g of test substance.***

There was no mortality. There were no indications of systemic toxicity. All animals had alopecia on day 1 and day 4, persisting in 5/5M and 2/5F to day 14. Two females had slight erythema on day 7 which had cleared by day 11. All rats gained weight in the period from day 0 to 7 and again from day 7 to 14.

At post-sacrifice necropsy no abnormalities were observed in any of the rats.

Dermal LD50 (rat) Males > 5050 mg/kg (0/5 died at this dose level)
Dermal LD50 (rat) Females > 5050 mg/kg (0/5 died at this dose level)

The granular solid CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot 0279954, Prod #: 823, TCR: 2993, containing 13.62% Fenhexamid and 53.86% Captan as active ingredients, is in toxicity category IV in terms of dermal toxicity..

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 21), Quality Assurance (p. 23), and [No] Data Confidentiality (p. 20) statements are provided. There is no flagging statement.

Procedure (including deviations from 870.1200): "Each animal was prepared on the day prior to treatment by clipping the dorsal surface of the trunk free of hair to expose not less than 10% of the total body surface area... All animals were treated with 5050 mg/kg of the test substance. Each dose was moistened with a sufficient amount of deionized water (0.3 mL/g of test substance) and was evenly applied to the exposure area of each animal. An individual dose was calculated for

each animal based on its Day 0 body weight just before exposure. The test substance was applied evenly to each exposure area in a thin, uniform layer. The area of application was covered with a 2 x 4 in. surgical gauze patch and secured with non-irritating adhesive tape. The trunk of each animal was then wrapped with vet wrap which was secured in place with non-irritating adhesive tape to prevent possible ingestion of the test substance... After 24 hours, the wrappings were removed. The test sites were gently washed with room temperature tap water and a clean cloth to remove as much residual test substance as possible..."

Results:

Dosage (mg/kg)	Number of Deaths/Number Tested		
	Males	Females	Combined
5050	0/5	0/5	0/10

Each gram of test material was mixed with 0.3 mL of deionized water before application.

Observations: There were no indications of systemic toxicity. All animals had alopecia on day 1 and day 4, persisting in 5/5M and 2/5F to day 14. Two females had slight erythema on day 7 which had cleared by day 11. All rats gained weight in the period from day 0 to 7 and again from day 7 to 14.

Gross Necropsy: At post-sacrifice necropsy no abnormalities were observed in any of the rats.

DATA REVIEW FOR PRIMARY DERMAL IRRITATION TESTING (870.2500, formerly §81-5)

Product Manager: 21 **Reviewer:** Byron T. Backus, Ph.D.
MRID No.: 45829702 (note: 2 other studies included in this MRID No.)

CITATION: Kuhn, J.O. CaptEvate 67.9 WDG: Final Report: Acute Dermal Irritation Study in Rabbits. Laboratory Study No. 7041-02; included under Arvesta TMN-0070. Unpublished study prepared by STILLMEADOW, Inc. Study Completion Date: September 5, 2002. MRID 45829702.

STUDY SPONSOR AND SUBMITTER: Arvesta Corporation, San Francisco, CA

TEST MATERIAL: CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot: 0279954, Prod #: 823, TCR: 2993. Described as fine rust brown granules containing 13.62% Fenhexamid and 53.86% Captan.

SPECIES: Rabbit; albino, New Zealand White (1 male & 2 females)
AGE: Young adult (approx. 14 weeks at exposure)
WEIGHT: Male: 3.025 kg; Females: 2.450 & - 2.600 kg
SOURCE: Ray Nichols Rabbitry, Lumberton, TX

EXECUTIVE SUMMARY: ***In a dermal irritation study (MRID 45829702), 0.5 g (moistened with 0.2 mL deionized water) of the granular solid CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot 0279954, Prod #: 823, TCR: 2993, containing 13.62% Fenhexamid and 53.86% Captan as active ingredients, was applied to a dermal site on each of 3 (1 male, 2 female) young adult (approximately 14 week old) rabbits (2.450-3.025 kg; source: Ray Nichols Rabbitry, Lumberton, TX), with 4-hr semioccluded exposure.***

All scores (1, 24, 48 & 72 hrs) for edema were zero. At one hour 2/3 sites scored "3" for erythema and 1/3 scored "2." At 24 hours 2/3 sites scored "1" for erythema and the other scored zero. One site scored "1" for erythema at 48 and 72 hrs. The primary irritation index (mean of scores at 1, 24, 48 & 72 hrs) = 1.0.

The test material, CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot 0279954, Prod #: 823, TCR: 2993, containing 13.62% Fenhexamid and 53.86% Captan as active ingredients, is in toxicity category IV in terms of dermal irritation potential.

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 34), Quality Assurance (p. 36), and [No] Data Confidentiality (p. 33) statements are provided. There is no flagging statement.

Procedure (including deviations from 870.2500): "Each animal was prepared on the day prior to treatment by clipping the dorsal area of the trunk free of hair to expose an area at least 8 x 8 cm... On Day 0, 0.5 of test substance moistened with 0.2 mL of deionized water was applied to each test site and covered with a 4 ply, 2.5 cm x 2.5 cm surgical gauze patch. Each patch was secured in place with a strip of non-irritating adhesive tape. The entire trunk of each animal was loosely wrapped with a semi-permeable dressing (orthopedic stockinette) which was secured on both edges with strips of tape to retard evaporation of volatile substances and to prevent possible ingestion of the test substance... After four hours, the patches and wrappings were removed. The test sites were gently washed with room temperature tap water and a clean cloth to remove as much residual test substance as possible..."

Results: All scores (1, 24, 48 & 72 hrs) for edema were zero. At one hour 2/3 sites scored "3" for erythema and 1/3 scored "2." At 24 hours 2/3 sites scored "1" for erythema and the other scored zero. One site scored "1" for erythema at 48 and 72 hrs. The primary irritation index (mean of scores at 1, 24, 48 & 72 hrs) = 1.0.

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D289843
2. **PC CODES:** 090209 Fenhexamid; 081301 Captan
3. **CURRENT DATE:** June 25, 2003
4. **TEST MATERIAL:** CaptEvate 67.9 WDG, TM-45002, Batch: 02, Lot: 0279954, Prod #: 823, TCR: 2993. Described as fine rust brown granules containing 13.62% Fenhexamid and 53.86% Captan.

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat/ STILLMEADOW Inc./Lab Study No. 7039-02; included in Arvesta TMN-0070/SEP-05-2002	45829702	Rat LD_{50}(M,F, combined)>2000 mg/kg (no mortalities among 5M & 5F dosed at this level), but <5050 (5/5M & 5/5F died following dosage at this level). Symptoms at 2000 mg/kg: very slight to moderate diarrhea, and (F only) *piloerection and sensitivity to touch.* All M had recovered by day 1 and all F by day 4. All rats dosed at 2000 mg/kg gained wt from day 0 to 7 and again day 7 to 14. No abnormalities found at post-sacrifice necropsy in rats dosed at 2000 mg/kg. At 5050 mg/kg signs included diarrhea, activity decrease, piloerection & salivation. 5/5F & 4/5M were dead by day 1; one male was dead by day 6. Necropsy findings at 5050 mg/kg included mottled lungs, brown/white liquid in stomach and small intestine, large intestine empty. Rat which died by day 6 had pale lungs, brown liquid in stomach, brown gel in small intestine & red/orange gel in large intestine.	III	A
Acute dermal toxicity/rat/ STILLMEADOW Inc./Lab Study No. 7040-02; included in Arvesta TMN-0070/SEP-25-02	45829702	Rat Dermal LD_{50}(M, F, combined) > 5050 mg/kg (no mortalities or signs of systemic dosage in 5M & 5F following 24-hr dermal exposure to this dose). All had alopecia on days 1 & 4, persisting in 5M & 2F to day 14. 2F had slight erythema day 7 which cleared by day 11. All gained wt days 0-7 and again from 7-14.	IV	A
Primary dermal irritation/ rabbit/STILLMEADOW Inc./Lab Study No. 7041-02; included in Arvesta TMN-0070/SEP-25-02.	45829702	3 rabbits used. All scores (1, 24, 48 & 72 hrs) for edema were zero. At one hr 2/3 scored "3" for erythema and 1/3 scored "2." At 24 hrs 2/3 scored "1" for erythema & at 48 & 72 hrs 1/3 scored "1." PII = 1.0	IV	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (870.1300, formerly §81-3)

Product Manager: 21 **Reviewer:** Byron T. Backus, Ph.D.
MRID No.: 45829703

CITATION: Carter, L. Captan 80 WP: Final Report: Acute Inhalation Toxicity Study in Rats. Lab Study No. 7038-02. Unpublished study prepared by STILLMEADOW Inc., Sugar Land, TX. Study Completion Date: July 23, 2002. MRID 45829703.

STUDY SPONSOR & SUBMITTER: Arvesta Corp., San Francisco, CA 94105

TEST MATERIAL: Captan 80 WP, Lot # 2052001 (WWL-A PG 259) 20 May 02; described as a fine light tan powder containing 80.3% Captan.

SPECIES: Rat; Sprague-Dawley
AGE(at exposure): Young adult (60 days old)
WEIGHT: Males: 251-299 g; Females: 187-212 g
SOURCE: Texas Animal Specialties, Humble, TX

EXECUTIVE SUMMARY: ***In an acute inhalation toxicity study (MRID 45829703), a group of 5 male (251-299 g) and 5 female (187-212 g) young (60 day old) adult Sprague-Dawley rats (source: Texas Animal Specialties, Humble, TX) received a 4-hr nose-only exposure to a gravimetrically-determined mean concentration of 2.70 mg/L Captan 80 WP, Lot # 2052001 (WWL-A PG 259) 20 May 02, a fine light tan powder containing 80.3% Captan. The mean (two measurements) MMAD was 3.7 μm, and the mean GSD was 5.5.***

There was no mortality (0/5M & 0/5F died). Symptoms (observed in all rats) were very slight to slight piloerection and very slight to slight activity decrease. All rats were normal by day 2. All gained weight from day 0 to 7, and 4/5M & 5/5F gained weight from day 7 to 14. There were no observable abnormalities at post-sacrifice necropsy.

Rat Inhalation LC_{50} (M) > 2.70 mg/L (0/5 died following 4-hr nose-only exposure)
Rat Inhalation LC_{50} (F) > 2.70 mg/L (0/5 died following 4-hr nose-only exposure)
Rat Inhalation LC_{50} (combined) > 2.70 mg/L (0/10 died following 4-hr nose-only exposure)

The test material, Captan 80 WP, Lot # 2052001 (WWL-A PG 259) 20 May 02, a fine light tan powder containing 80.3% Captan, is in toxicity category IV in terms of inhalation toxicity, as the rat LC50 >2.70 mg/L.

Study Classification: Acceptable

COMPLIANCE: Signed and dated GLP Compliance (p. 3), Quality Assurance (p. 5), and [No] Data Confidentiality (p. 2) statements are provided. There is no flagging statement.

Procedure (including deviations from 870.1300): "The aerosol was generated by a Gem T Trost Air Mill which aspirated the test substance from a motorized revolving disc delivery system coupled to the mill, then sprayed the resulting aerosol directly into the exposure chamber... The animals were exposed to an aerosol generated from the undiluted test substance (fine powder) for a period of four hours..."

Results:

Mean Exposure Concentration (mg/L) (Gravimetrically Determined)	Number of Deaths/Number Tested		
	Males	Females	Combined
2.70	0/5	0/5	0/10

The nominal concentration of Captan 80 WP was 11.4 mg/L.

Clinical Observations: Symptoms (observed in all rats) were very slight to slight piloerection and very slight to slight activity decrease. All rats were normal by day 2. All gained weight from day 0 to 7, and 4/5M & 5/5F gained weight from day 7 to 14.

Gross Necropsy: There were no observable abnormalities at post-sacrifice necropsy.

Chamber Atmosphere		
Gravimetric Conc. (mg/L)	**MMAD (μm)**	**GSD**
2.70	3.7	5.5

Particle Size Distribution: >47% of the particles by mass an equivalent particle diameter less than 4.4 μm.

Chamber Environment	
Internal Chamber Volume	500 L
Mean Air Flow Rate	184 LPM
Chamber Temperature (range)	70° - 72°F
Relative Humidity (range)	65-69%

ACUTE TOX ONE-LINERS

1. **DP BARCODE:** D289843
2. **PC CODE:** 081301 Captan
3. **CURRENT DATE:** June 25, 2003
4. **TEST MATERIAL:** Captan 80 WP, Lot # 2052001 (WWL-A PG 259) 20 May 02; described as a fine light tan powder containing 80.3% Captan.

Study/Species/Lab Study #/Date	MRID	Results	Tox. Cat.	Core Grade
Acute Inhalation Toxicity/ rat/STILLMEADOW Inc./Lab Study No. 7038-02/JUL-23-02.	45829703	LC_{50} rat (M, F, combined) > 2.70 mg/L (0/5M & 0/5F died). Symptoms: very slight to slight piloerection & very slight to slight activity decrease. All rats were normal by day 2. No abnormalities observed at post-sacrifice necropsy. MMAD = 3.7 µm; GSD = 5.5.	IV	A

Core Grade Key: **A =Acceptable, S = Supplementary, U = Unacceptable, V = Self Validated**